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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/401,636	09/22/1999	LARS T. HELLMAN	10223/006001	4922

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MARK S ELLINGER
FISH & RICHARDSON
60 SOUTH SIXTH STREET
SUITE 3300
MINNEAPOLIS, MN 55402

EXAMINER

JAMROZ, MARGARET E

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 12/04/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	09/401,636	Applicant(s)	HELLMAN, LARS T.
Examiner	Margaret E Jamroz	Art Unit	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 09 October 2001.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,2,4-11 and 25-54 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-2,4-11, 25-54 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- 1) Certified copies of the priority documents have been received.
- 2) Certified copies of the priority documents have been received in Application No. _____.
- 3) Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

4) Interview Summary (PTO-413) Paper No(s) _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

Art Unit: 1644

DETAILED ACTION

1. The Art Unit location and the examiner of your application in the PTO have changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Megan Jamroz, Art Unit 1644, Technology Center 1600.
2. Applicant's amendment, filed 10/9/2001 (Paper No. 17), is acknowledged.
Claims 1-2, 4-11, and 25-54 are pending.
3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed*.
4. In view of the amendment, only the following rejections remain.
5. Claims 1-2, 4-11, and 25-54 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "an immunogenic polypeptide comprising a nonself IgE CH2 domain, a self IgE CH3 domain, and a nonself IgE CH4 domain", does not reasonably provide enablement for:
 - (A) "An immunogenic polypeptide comprising a self IgE portion and a nonself IgE portion, and wherein said self IgE portion comprises at least a portion of a CH3 domain of IgE" (claim 1),
 - (B) "An immunogenic polypeptide of claim 1 wherein the nonself portion comprises a first region and a second region, said self IgE portion being located between said first and second regions of said nonself IgE portion" (claim 5),
 - (C) "The immunogenic polypeptide of claim 5, wherein said first region comprises at least a portion of an IgE CH2 domain" (claim 6), or
 - (D) "The immunogenic polypeptide of claim 5, wherein said first region comprises at least a portion of an IgE CH4 domain" (claim 7),

for the same reasons set forth in Paper No. 9, mailed 07/03/00, Paper No. 13, mailed 01/02/01, and Paper No. 16, mailed 06/28/01.

6. Applicant's arguments filed 10/09/2001 have been fully considered but they are not persuasive.

Applicant's argument is that claims 1, 25, and 48 indicate that the immunogenic polypeptide must contain at least a portion of a CH3 domain of IgE and must induce an anti-self IgE response wherein the self IgE portion consists essentially of an N-terminal portion of a CH3 domain of IgE.

It is the examiner's position that the specification is enabling for the entire CH2, CH3, and CH4 domains, but is not enabling for "at least a portion" of these domains. Applicant defined the specific "portion" of the CH3 domain that is necessary to impart function to the domain is the N-terminal portion (claim 33), however, "an N-terminal portion" could consist of one amino acid of the N-terminal "portion" and meet the claimed limitation. In the absence of a defined sequence, the claims as broadly recited are not enabled.

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7. Claims 1-2, 4-11, and 33-40 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

Applicant's position is that Figure 2 identifies multiple polypeptides that contain a self-IgE portion consisting essentially of an N-terminal portion of a CH3 domain of IgE. Applicant's position is that the inventor was in possession of methods for expressing, purifying, and detecting polypeptides within the scope of the presently claimed invention, as well as their use to induce an immune response.

It is the examiner's position that the specification and claims as originally filed do not provide support for the claimed:

- (A) "An immunogenic polypeptide ... wherein said non-self IgE portion consists essentially of a CH2 domain" (claim 1) or
- (B) "An immunogenic polypeptide ... wherein said non-self IgE portion consists essentially of an N-terminal portion" (claim 33).

Figure 2 does not provide support for the generic, or subgeneric, claims encompassing the recited limitations. In Gentry Gallery, Inc. v. The Berkline Corp., 134 F. 3d 1473, 1479-80, 45 USPQ2d 1498, 1503 (Fed. Cir. 1998), the court acknowledged that while a claim may be broader than the specific embodiment disclosed in the specification, the "claims may be no broader than the supporting disclosure". Thus, a narrow disclosure will limit claim breadth.

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Jamroz, whose telephone number is (703) 308-8365. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Margaret (Megan) Jamroz, Ph.D.

Patent Examiner

Technology Center 1600

December 1, 2001

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Christina Chan

CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP 1640

1640